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10/031,897	01/22/2002	Robert Scott	6517-11-BHJ	8243

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Evan J Federman
Warner Lambert Company
Legal Division
201 Tabor Road
Morris Plains, NJ 07950

EXAMINER

KLEMANSKI, HELENE G

ART UNIT

PAPER NUMBER

1755

DATE MAILED: 09/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

7

Office Action Summary

Application No.

10/031,897

Applicant(s)

SCOTT ET AL.

Examiner

Helene Klemanski

Art Unit

1755

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 42-78 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,43,45-49,52-59,61,63,64,66 and 69-76 is/are rejected.
- 7) ☒ Claim(s) 42,44,50,51,60,62,65,67,68,77 and 78 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. 6) ☐ Other: .

Art Unit: 1755

DETAILED ACTION**Response to Papers Filed**

1. The papers filed on **May 20, 2002** (certificate of mailing dated **May 9, 2002**) have not been made part of the permanent records of the United States Patent and Trademark Office (Office) for this application (37 CFR 1.52(a)) because of damage from the United States Postal Service irradiation process. The above-identified papers, however, were not so damaged as to preclude the USPTO from making a legible copy of such papers. Therefore, the Office has made a copy of these papers, substituted them for the originals in the file, and stamped that copy:

**COPY OF PAPERS
ORIGINALLY FILED**

If applicant wants to review the accuracy of the Office's copy of such papers, applicant may either inspect the application (37 CFR 1.14(d)) or may request a copy of the Office's records of such papers (*i.e.*, a copy of the copy made by the Office) from the Office of Public Records for the fee specified in 37 CFR 1.19(b)(4). Please do **not** call the Technology Center's Customer Service Center to inquiry about the completeness or accuracy of Office's copy of the above-identified papers, as the Technology Center's Customer Service Center will **not** be able to provide this service.

If applicant does not consider the Office's copy of such papers to be accurate, applicant must provide a copy of the above-identified papers (except for any U.S. or foreign patent documents submitted with the above-identified papers) with a statement that such copy is a complete and accurate copy of the originally submitted documents. If applicant provides such a copy of the above-identified papers and statement within **THREE MONTHS** of the mail date of this Office action, the Office will add the original mailroom date and use the copy provided by applicant as the permanent Office record of the above-identified papers in place of the copy made by the Office. Otherwise, the Office's copy will be used as the permanent Office record of the above-identified papers (*i.e.*, the Office will use the copy of the above-identified papers made by the Office for examination and all other purposes). This three-month period is not extendable.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in the European Patent Office on May 16, 2000. It is noted, however,

Art Unit: 1755

that applicant has not filed a certified copy of the EPO 00401333.0 application as required by 35 U.S.C. 119(b).

Specification

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: no literal antecedent basis is seen for the phrases:

(1) “wherein the pullulan is 85% to 95% by weight, and the setting system is 5% to 15% by weight” in claim 49;

(2) “wherein the cations are less than 5% by weight, preferably 0.01% to 3% by weight, more preferably 0.5% to 2% by weight” in claim 50 (applicants disclose on page 7, lines 6-9 that the amount of cations are preferably less than 3% by weight, especially 0.01% to 1% by weight, with a preferred concentration of less than 2% by weight) and

(3) “wherein the sequestering agent is less than 5% by weight, preferably 0.01% to 3% by weight, more preferably 0.5% to 2% by weight” in claim 51 (applicants disclose on page 11, lines 3-6 that the amount of the sequestering agent is preferably less than 3% by weight, especially 0.01% to 1% by weight).

The examiner suggests the incorporation of this phrase into the specification or the claims amended accordingly.

Art Unit: 1755

Claim Objections

4. Claims 43, 50, 51, 64, 73, 75, 77 and 78 are objected to because of the following informalities: in claims 43, line 2, the term "NA+" should be replaced with the term "Na+"; in claim 50, line 1, the phrase "amount of" should be inserted between the terms "the" and "cations" and in claim 51, line 1, the phrase "amount of" should be inserted after the term "the". Appropriate correction is required.

The following phrases are also being objected to because of the following reasons:

(1) in claim 50, lines 2 and 3, the phrases "preferably 0.01% to 3% by weight, more preferably 0.5% to 2% by weight";

(2) in claim 51, lines 2 and 3, the phrases "preferably 0.01% to 3% by weight, more preferably 0.5% to 2% by weight";

(3) in claim 64, line 2, the phrase "preferably a pharmaceutical capsule";

(4) in claim 73, line 2, the phrase "such as room temperature";

(5) in claim 75, line 2, the phrase "preferably 15 to 40% by weight of the aqueous solution";

(6) in claim 77, line 2, the phrase "preferably, 0.01 to 1% by weight of the aqueous solution" and

(7) in claim 78, lines 2 and 3, "preferably, 0.01 to 1% by weight of the aqueous solution".

Applicants should note that the terms "preferably", "more preferably" and "such as" and the phrases that follow them do not further limit the claims. For example, in

Art Unit: 1755

claim 50, it is the examiner's position that the amount of the cations is less than 5% by weight and the remaining amounts after the terms "preferably" and "more preferably" do not extend the scope of that claim. The examiner suggests the deletion of the above phrases and adding each limitation as a new dependent claim.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 43, 45, 47, 48, 52-54, 57-59, 61, 66 and 69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 43, 45, 47, 48, 52-54, 57-59, 61, 66 and 69, the phrases "selected from the group comprising", "selected from" are considered indefinite since this is improper Markush language. It is the examiner's position that other materials could be present in the Markush group that were not intended by applicants by the use of the phrases "selected from the group comprising", "selected from" since these phrases do not exclude other materials. The examiner suggests the language "selected from the group consisting of" in place of these phrases.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1755

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 46, 52, 56 and 74 are rejected under 35 U.S.C. 102(b) as being anticipated by JP53/079972.

JP53/079972 teach a film forming composition comprising pullulan, a water-soluble substance such as sodium arginate or starch (i.e. hydrocolloid setting system) and water. See the abstract. The film forming composition as taught by JP53/079972 appears to anticipate the present claims.

9. Claims 1, 46-49, 52-57, 63, 64 and 70-76 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakamura et al.

Nakamura et al. teach a film forming composition comprising by weight pullulan and heteromannan such as guar gum, tara gum, locust bean gum and konjak mannan (i.e. hydrocolloid setting system). The heteromannan is present in an amount less than the pullulan used such as 1-80% of the pullulan. Optional additives such as a coloring agent and flavor may also be added to the composition. The film forming composition is used to make molded articles such as capsules. See col. 1, lines 10-15, col. 2, lines 10-50, Experiment 1, Table I, Experiment 2, examples 1 and 3 and claims 1 and 4-7. The film forming composition as taught by Nakamura et al. appears to anticipate the present claims.

10. Claims 1, 46-48, 53, 63 and 74-76 are rejected under 35 U.S.C. 102(b) as being anticipated by EP0328317.

EP0328317 teach an edible film comprising an aqueous mixture of curdlan (i.e. hydrocolloid setting system) and 0.1-20 parts by weight per part by weight of curdlan of a water-soluble macromolecular substance such as pullulan. The films may contain foodstuffs and can also be used as edible casings. See page 2, lines 3-58, example 3 and claims 1-3. The film forming composition as taught by EP0328317 appears to anticipate the present claims.

Allowable Subject Matter

11. Claims 42, 44, 50, 51, 60, 62, 65, 67, 68, 77 and 78 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. Claims 43, 45, 58, 59, 61, 66, and 69 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

13. The following is a statement of reasons for the indication of allowable subject matter: The cited references fail to teach or fairly suggest a film forming composition: (1) comprising a setting system that further comprises cations; (2) comprising a setting system that further comprises at least one sequestering agent; (3) comprising the specific coloring agents as claimed in claims 58 and 59; (4) comprising one or more surfactants; (5) that forms a container wherein the container comprises a coating and

Art Unit: 1755

(6) in the form of an aqueous solution that further comprises cations and/or one or more sequestering agents.


Conclusion

The remaining references listed on forms 892 and 1449 have been reviewed by the examiner and are considered to be cumulative to or less material than the prior art references relied upon in the above rejections.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helene Klemanski whose telephone number is 703-308-3745. The examiner can normally be reached on Monday-Friday 5:30-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Bell can be reached on 703-308-3823. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.


Helene Klemanski
Primary Examiner
Art Unit 1755



HK
September 8, 2003